In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

VIDEOTAPED DEPOSITION OF MICHAEL C. COTUGNO

June 04, 2015

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No. 2419

Master Dkt. 1:13-md-02419-RWZ

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THIS DOCUMENT RELATES TO ALL SUITS AGAINST THE SAINT THOMAS ENTITIES

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THIS DOCUMENT RELATES TO ALL CASES

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VIDEOTAPED DEPOSITION OF MICHAEL C. COTUGNO

Thursday, June 4, 2015

9:04 a.m.

Nutter McClennen & Fish LLP

Seaport West

155 Seaport Boulevard

Boston, Massachusetts 02210

Michelle Keegan, Court Reporter

Q. Looking at the report, or if you have an independent recollection, what was different about what you actually did inside the facility in 2012 versus 2008, if anything?
A. I don't recall any differences.
Q. Did you look at documentation in 2012?
A. We did.
Q. Did you review policies and procedures in 2012?
A. We did.
Q. Did you look around the facility in 2012?
A. We did.
Q. Did you look into the clean room, or do you remember?
A. I recall looking into the clean room.
Q. Do you recall going into the clean room?
A. I do not recall going into the clean room.
Q. Generally when you do these vendor audits, do you go into the clean room?
MR. ROBERTSON: I object. Temporal. Back then generally did he?
Q. Prior to 2012 when you did these audits, did you go into the clean room?
A. I, on any of the audits, have never gone in physically -- I don't recall on any of these audits

physically going into a clean room. Always looking into a clean room.

Q. Has Mr. McAteer accompanied you on every compounding pharmacy vendor audit from '07 to '12, or did he from '07 to '12?

A. Yes.

Q. Do you have any recollection of Mr. McAteer ever being allowed to go into the clean room on one of these vendor audits?

A. I don't recall him going into the clean room either.

Q. Do you know why that is, why -- Well, let me ask this to give it a little foundation and avoid three objections.

Have you or Mr. McAteer during any of these vendor audits asked to go in the clean room and the vendor said no, we don't allow that?

A. I don't recall being denied or I don't recall asking either.

Q. Why not? Why do you-all not go into the clean room during these vendor audits?

A. Usually -- and there were multiple places. Usually we can view into the clean room via a window.

Q. On page 140, which is the third page of the

A. That is correct.
Q. You're not sure which visit it was?
A. Correct.
Q. So do you remember if that was in the back of the building or in the middle center of the building?
A. I don't recall.
Q. Okay. Now, in neither visit did you ever -- you or Fran McAteer never entered the clean room area. Correct?
A. That is correct.
Q. You never entered the anteroom where they gown up?
A. Correct.
Q. You never entered the prep room?
A. Correct.
Q. And you never entered the formal cleaning room -- clean room?
A. Correct.
Q. So you never looked at any of the equipment that was in the clean room. Correct?
A. Only what I could see through the window.
Q. What you could see through a window. Okay. And we're going to talk more about that window.
You never went into the rooms and did any kind

of detailed examination of those clean rooms?

A. Correct.

Q. And if I understand it correctly from this report, at least Exhibit 299 says that it was from 10:00 to 12:00 o'clock, the whole visit?

A. This is 2008?

Q. Yeah.

A. I don't recall the time frames, but that --

Q. Do you remember the e-mails where Barry says, I'll give you two hours, 10:00 to 12:00?

A. Right. So we would have been there around that time.

Q. And I'm not holding you to the minute, but approximately.

So the whole visit between arriving, having discussions with Mr. Cadden, looking at the documents that you looked at, walking around the facility, that whole visit took approximately two hours. Correct?

A. I don't know when it ended.

Q. Okay. Well, do you have any memory that's different than what's on this report?

MR. ROBERTSON: I object to the form.

A. That's what's on the agenda. I don't recall whether we finished early or stayed late.

the higher temperature will encourage more growth. Correct?

A. That's my understanding, yes.

Q. And what, if anything, did you do to follow up on that to see if NECC changed their temperature for that?

A. I don't recall following up on it.

Q. And let's turn back to that -- by the way, the rotating out the sporicidal agents, the reason you rotate sporicidal agents into your cleaning program, that's for the -- it's really for safety reasons. Correct? To make sure there's no fungal growth. Correct?

A. Correct.

Q. And then let's just look at one other thing from this. On the narrative on BW_706, the second paragraph, second-to-last sentence, "NECC is moving soon to a new area in the same building complex. BWH should observe the new operation when completed." Do you see that?

A. Yes.

Q. Did you follow up to find out when they were moving to the new area?

A. I don't recall asking for a date, a specific

date or a discussion around an exact date.

Q. Do you remember scheduling an audit so that the new operation could be observed?

A. We did schedule an audit in 2012.

Q. Four years later?

A. Correct.

Q. Between 2008 and 2012, did you receive any type of sterility tests, batch certification reports, on a regular basis from NECC?

A. I don't recall receiving regular reports or actually any reports.

Q. Any equipment validation reports, for example?

A. I don't recall receiving any reports from them.

Q. Did you have a policy where you required your vendors -- your compounding sterile product vendors to report to you if any of their pharmacists or pharmacy techs' licenses were suspended by the board of pharmacy?

A. I don't recall the policy stating about licenses.

Q. So after that 2008 site visit to NECC, did you tell Mr. Churchill, your boss, that you had only been there for approximately two hours?

A. I don't recall a discussion around how long we were there.

Q. Okay. So can you read what you wrote to Barry Cadden in March of 2012, first paragraph.

A. "It has been about four years since we last visited NECC. Per our internal policy, we are due to come out for another visit. It is also a hospital joint commission survey year. We are hearing that the surveyors are asking hospitals to provide information on the sterile compounding facilities/pharmacies they receive product from."

Q. What is the hospital joint commission that you're referring to there?

A. The joint commission is an agency that accredits hospitals for the government with regards to CMS and Medicare, Medicaid, is my understanding.

Q. And do they come in and do a audit of your facility?

A. They do.

Q. How long does that take for them to do that?

A. They are there usually for a week.

Q. A week. And they audit your pharmacy?

A. Sometimes.

Q. Sometimes. That sounds like a real audit.

MR. TARDIO: Objection.

MR. ROBERTSON: Wait for a question.

went out and did a site visit. Correct? And then you wanted something from NECC that says something about their quality. Correct?

A. Correct.

Q. Just in case the joint commission asked for it, you'd have it. Correct?

A. Correct.

Q. And then read the second line of that paragraph that you wrote to Barry Cadden in March of 2012. "They," the second line of Paragraph 2.

A. "They are expecting that BWH do this and review this information to ensure our patient safety."

Q. And the "they" in that sentence is again the joint commission?

A. Correct.

Q. And Brigham and Women's -- BWH is Brigham and Women's Hospital. Correct?

A. Correct.

Q. And then you give him some dates and times. Do you see that? To set up the visit.

A. Correct.

Q. And do you say, "I would like to try to start at 8:00 a.m. and finish no later than 1:00 p.m."?

A. Correct.

Q. So you're looking for five hours for the site visit. Correct?
A. Correct.
Q. And then you say in the next paragraph, "I have a pharmacy resident with me that I would like to bring along." What was that referring to?
A. We trained pharmacy residents. These are people who have graduated pharmacy school, so they're not pharmacy interns. And then they do a year residency at the hospital.
Q. Okay. Did you send him an audit form for completion -- audit survey form for completion with that e-mail?
A. Yes.
Q. With this e-mail?
A. Oh, I don't recall. I don't see that there's one of those little things --
Q. It doesn't show an attachment?
A. It doesn't show an attachment. So I would say it wasn't on this one because it's not there.
Q. You didn't send him that. And you didn't send him a proposed agenda for the site visit, nor did you ask him for any specific records to be compiled for review at the site visit, did you?

MS. KELLY: Objection.
A. Not in that e-mail.
Q. Okay. So let's move to Exhibit 310, which is the next e-mail that we could find concerning this. And can you identify Exhibit 310, please?
A. It is an e-mail from me to Barry Cadden, with Fran McAteer cc'd, about the NECC site visit.
Q. What's the date of this?
A. The date of the -- well, the date of the top e-mail is May 3rd, 2012.
Q. And the first sentence says, "I just" -- "Hi, Barry. I just want to make sure we're still on for the BWH vendor audit on Friday, May 4th, at 8:30." Correct?
A. Correct.
Q. So this is a day before you're about to go out on your 2012 site visit. Correct?
A. Correct.
Q. And now you do attach something, don't you?
A. I don't recall.
Q. Look at the attachments. Look at the front of the e-mail. Look at the attachments.
A. Where would I --
Q. Right under "Subject matter" there's a line called "Attachments."

in the front, but I don't recall at the time making any note of what those businesses were or whether they would have said "recycling."

And now -- I would then be mixing my knowledge of what I know now of a recycling facility and of what it might have said then didn't register as recycling. Now I do know that because of current events.

Q. Did you make any inquiry of Mr. Cadden during either the 2008 or 2012 visits as to what other businesses were operating at that site?

A. I don't recall asking him that.

Q. So you were asked some questions on direct examination about whether you asked -- whether you asked Cadden during any of these visits whether they had ever had a lawsuit or settled a lawsuit. And I think you said you don't remember asking that question.

Did you ask him whether any of his -- the drugs that had been compounded by NECC had ever killed someone?

A. No, I never asked that question.

Q. Do you know what the Pharmacy Compounding Accreditation Board is?

A. I have heard of it before.

Q. Did you know what it was in 2008, 2012?

A. It's PCAB, right?
Q. PCAB.
A. I would have known.
Q. Did you ask Barry Cadden whether they were accredited by PCAB at either the 2008 or 2012 inspections?
A. I don't recall if we asked him that.
Q. Did you take any surface samples for testing at either visit?
A. No.
Q. By the way, when -- we saw a couple order forms before for drugs that Brigham and Women's submitted to NECC. When NECC -- when Brigham and Women's submitted scripts or order forms for drugs from NECC, did they supply the patient weights, maximum dosage per hour, and route of administration for each of the drugs that were ordered? You can see it on the form.
A. It's not on those order forms, no.
Q. Do you have any knowledge that Brigham and Women's ever supplied any of that information to NECC?
A. We sent them prescriptions for some items, individual patient prescriptions for items. I'm not aware that weight was on it.
Q. Or maximum dosage per hour. You know what that

is. Correct?
A. Yes. Not that exact term.
Q. Or route of administration?
A. I don't recall seeing that on any of them.
Q. Okay. You know what maximum valid dilution is, or is that beyond your --
A. I've heard the term, but I wouldn't credit myself with knowing what that definition is and how it's applied.
Q. Okay. So let's just take another look at this audit report from 2012, Exhibit 316. Keep the 2008 audit report just in front of you but 299 too. I just want to go through one other comparison with both of those reports.
On page BW_138 of Exhibit 316, the 2012 report, under "General," do you see the sentence, "All documentation seemed adequate and compliant to GMP"? Do you see that?
A. I do.
Q. What is GMP?
A. Good Manufacturing Practices.
Q. Okay. So what did you understand Mr. McAteer telling you when he wrote that?
A. Well, Good Manufacturing Practices is something

manufacturers through the FDA comply with. That's their regulations, guidelines.

Q. So what did you understand that Mr. McAteer was telling you in his report?

MR. ROBERTSON: I object.

A. I don't recall what I would have thought at the time. I know what it means reading it now.

Q. Okay. Do you think you knew what GMP was back in 2012?

A. I did.

Q. GMP is a little stricter than USP 797. Is that correct?

A. Yes.

Q. Did you think that NECC was GMP compliant?

MR. ROBERTSON: I object.

A. No.

Q. Did you ask Mr. McAteer, Why are you saying they're compliant with GMP?

A. I did not.

Q. Do you know why you didn't ask that?

A. I don't recall.

Q. Did you read the report before you signed it?

A. I did read the report.

Q. Would you have liked NECC to be GMP compliant

back in 2012?

MR. ROBERTSON: I'm going to object.

A. GMP is a higher standard. GMP would be preferred over USP.

Q. It's a good thing. Right?

A. It's a good thing.

Q. Okay. So there were three recommendations by Mr. McAteer after the 2012 site visit. One was "Establish USP 797 action limits for viable air sampling." And it says that "Action limits are in place; however, the action limits for viable air are greater than 2 CFU/M3, which are not aligned with current USP 797 action levels of greater than 1 CFU/M3."

Do you see that?

A. I do.

Q. So what he's saying there was that was not compliant with USP 797. Correct?

A. That's what that says.

Q. Okay. That conflicts with the statement on the first page -- second page of the report, BW_137, where Mr. McAteer said, "Overall, NECC is compliant for USP 797 regulations." Correct?

MR. ROBERTSON: I will object. And I think we've established he doesn't know the foundation of 797

to make such a fine distinction.

MR. ELLIS: This is not a distinction.

Q. You said you understood from Recommendation Number 1 that they were not compliant with USP 797. Correct?

A. (No verbal response)

Q. You understood from reading Recommendation Number 1 on the action limits for viable air sampling that Mr. McAteer was telling you they're not compliant with USP 797 on this. Correct?

MR. ROBERTSON: I object.

A. That's what is in the report.

Q. I'm not asking you whether you know it's true, whether you completely understand it. What he's telling you there is that at least with respect to this, they're not in compliance with USP 797?

A. Yes, that's what he's telling me.

Q. But on the page before the report, Mr. McAteer had written, "Overall, NECC is compliant for USP 797 regulations."

A. That's what he wrote on the -- yes.

Q. Well, did you think, well, maybe there's some inconsistencies there?

MR. ROBERTSON: I object. Did he have that

thought in 2012?

MR. ELLIS: When he read the report before he signed it.

Q. Did you say maybe this isn't quite accurate?

A. To be honest --

Q. Yes. I'm asking you to be very honest here today.

A. Sorry. I do recall the CFU limit registering in my mind. I actually believe I took out my copy of USP to look at that. That rings a bell to me of when I saw it I said: Gee, I wonder what -- that doesn't -- I didn't know that -- I was confused by that statement at the time.

Q. Okay. By the way, did you do anything to follow up after this report with NECC to see if they'd come into compliance with USP 797 on their action limits for viable air sampling?

A. I don't recall any followup discussions with NECC after this.

Q. Did you send this report to NECC after the site visit?

A. I don't recall. And I don't know if that was -- if we did that with all the vendors. We may have done that with some of the vendors, but I don't recall

person was working.

Q. But you didn't answer my question. Did you see --

MR. ROBERTSON: Whoa, whoa, whoa.

Q. Did you see then gowning, hand washing, and whether they were complying with aseptic technique?

A. I don't recall what they were doing.

Q. And what about Slide Number 30? Does that look familiar, the one entitled "Facility tour goals. Observe actual compounding process in action"?

A. Whether it was this exact slide or similar-type slides, there is wording in here that I recognize.

Q. Okay. And what this was about was, when you're doing one of these vendor audits of a compounding pharmacy who's supplying sterile products to a healthcare provider, that you should observe actual compounding process in action.

Look for compliance with established SOPs, meaning that -- not just that they have procedures, but they're actually following the procedures in action. Look for system double-checks. Look for use of medication safety technology. Look for the pharmacist's role in product preparation and validation. Observe them during the documentation processes. Check for

documentation and calibration of any automated devices that may be in use.

Did you do any of that when you were at NECC in either 2008 or 2012, sir?

A. During the tour, there were people working. I don't recall exactly what pieces of that -- I couldn't say exactly which pieces -- recall which pieces they were doing.

Q. Okay. But you never went into the clean room on either visit?

MR. TARDIO: Objection.

A. We did not go in the clean room.

MR. ELLIS: I'm going to mark this as Exhibit 344.

(Exhibit Number 344
marked for identification)

Q. Do you recognize what I've marked as Exhibit 344?

A. Correct. I do.

Q. What is this, sir?

A. It's a presentation on implementing sterile product services.

Q. Okay. And did you give this at a -- the South Carolina Society of Health-System Pharmacists on